

Kansas Department of Health and Environment
Proposed Amended Regulation

Article 35. Radiation

Part 3. Licensing of Sources of Radiation

28-35-181m. Specific licenses to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material for medical use. An application for a specific license to manufacture, prepare, or distribute radiopharmaceuticals containing radioactive material and used by persons as specified in part 6 of these regulations shall not be approved unless the applicant meets the requirements of this regulation and all other applicable requirements of these regulations.

(a) The applicant shall meet the requirements specified in K.A.R. 28-35-180a.

(b) The applicant shall submit evidence of ~~at~~ either of the following:

(1) ~~(A)~~ The radiopharmaceutical containing radioactive material is subject to the federal food, drug and cosmetic act or the public health service act and will be manufactured, labeled, and packaged in accordance with a new drug application (NDA) approved by the food and drug administration (FDA), a biologic product license issued by the FDA, or a "notice of claimed investigational exemption for a new drug" (IND) accepted by the FDA; ~~or~~ .

~~(B)~~ (2) The manufacture and distribution of the radiopharmaceutical containing radioactive material is not subject to the federal food, drug, and cosmetic act or the public health service act.

(c) The applicant shall submit evidence of at least one of the following:

~~(2)~~ (1) The applicant is registered or licensed with the U.S. food and drug administration as a drug manufacturer.

~~(3)~~ (2) The applicant is registered or licensed with a state agency as a drug manufacturer.

~~(4)~~ (3) The applicant is licensed as a pharmacy by the state board of pharmacy.

~~(5)~~ (4) The applicant is operating as a nuclear pharmacy within a federal medical institution.

~~(e)~~ (d) The applicant shall submit the following information on the radionuclide:

(1) The chemical and physical form of the material;

(2) the packaging in which the radionuclide is shipped, including the maximum activity per package; and

(3) evidence that the shielding provided by the packaging of the radioactive material is appropriate for the safe handling and storage of radiopharmaceuticals by group licensees.

~~(d)~~ (e) (1) The applicant shall submit a description of the following:

(A) A label that shall be affixed to each transport radiation shield, whether the shield is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution. The label shall include the following:

(i) The radiation symbol and the words “CAUTION - RADIOACTIVE MATERIAL” or “DANGER - RADIOACTIVE MATERIAL”;

(ii) the name of the radioactive drug and the abbreviation; and

(iii) the quantity of radioactivity at a specified date and time. For radioactive drugs with a half-life greater than 100 days, the time may be omitted; and

(B) a label that shall be affixed to each syringe, vial, or other container used to hold a radioactive drug to be transferred for commercial distribution. The label shall include the radiation symbol and the words “CAUTION - RADIOACTIVE MATERIAL” or “DANGER - RADIOACTIVE MATERIAL” and an identifier that ensures that the syringe, vial, or other container can be correlated with the information on the transport radiation shield label.

(2) The labels, leaflets or brochures required by this regulation shall be made in addition to the labeling required by the FDA. The labels, leaflets or brochures may be separate from the FDA labeling, or with the approval of the FDA, the labeling may be combined with the labeling required by the FDA.

~~(e)~~ (f) All of the following shall apply to each licensee described in ~~subsection (b)~~ paragraph (c)(3) or (c)(4), or both:

(1) The licensee may prepare radioactive drugs for medical use, if each radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraphs (2) and (4) of this subsection, or an individual under the supervision of an authorized nuclear pharmacist.

(2) The licensee may allow a pharmacist to work as an authorized nuclear pharmacist if at least one of the following conditions is met:

(A) The pharmacist qualifies as an authorized nuclear pharmacist.

(B) The pharmacist meets the requirements specified in 10 CFR 35.55 (b) and 35.59, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist.

(C) The pharmacist is designated as an authorized nuclear pharmacist in accordance with paragraph (4) of this subsection.

(3) The actions authorized in paragraphs (1) and (2) of this subsection shall be permitted in spite of more restrictive language in license conditions.

(4) The licensee may designate a pharmacist as an authorized nuclear pharmacist if the individual was identified on or before December 2, 1994 as an “authorized user” on a nuclear pharmacy license issued under this part.

(5) Each licensee shall provide the following to the department no later than 30 days after the date that the licensee allows, pursuant to paragraphs (2)(A) and (2)(C) of this subsection, the individual to work as an authorized nuclear pharmacist:

(A) A copy of each individual’s certification by the board of pharmaceutical specialties, the department or agreement state license, or the permit issued by a licensee of broad scope; and

(B) a copy of the state pharmacy license or registration.

~~(F)~~ (g) Each licensee shall possess and use instrumentation to measure the radioactivity of radioactive drugs. Each licensee shall have procedures for using the instrumentation. Each licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs before transfer for commercial distribution. Each licensee shall meet the following requirements:

~~(A)~~ (1) Perform tests before initial use, periodically, and following repair on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument, and make adjustments if necessary; and

~~(B)~~ (2) check each instrument for constancy and proper operation at the beginning of each day of use.

~~(g)~~ (h) Nothing in these regulations shall exempt the licensee from the requirement to comply with applicable FDA requirements and other federal and state requirements governing radioactive drugs. (Authorized by and implementing K.S.A. 48-1607; effective, T-86-37, Dec. 11, 1985; effective May 1, 1986; amended Dec. 30, 2005; amended P-_____.)